K062529

510(k) Summary

807.92(c)

OCT - 5 2006

Sponsor

807.92(a)(1)

Submitter
TAKARA BELMONT USA, INC.
BELMONT Equipment Division
101 Belmont Drive
Somerset, New Jersey 08873-1204

Contact Person: Robert Schiff
Telephone: 973-227-1830

Date Prepared: September 26, 2006

Manufacturing Facility:
Asahi Roentgen Ind. Co., Ltd
376-3 Tsukiyama-cho, Kuze,
Minami-ku, Kyoto, Japan

Corresponding Official: Mr. Masahiro Kanaya

Device Name

807.92(a)(2)

Proprietary Name:	BELMAX CM Model X168
Common/Usual Name:	Dental Panoramic and Cephalometric X-Ray System
Classification Name:	System, X-Ray, Extraoral Source, Digital
Regulation Number:	872.1800
Classification Code:	MUH

Predicate Devices

807.92(a)(3)

Predicate Device #1:	Takara Belmont ANA-BEL, ANA-BEL CM, K040748
Predicate Device #2:	Takara Belmont ADR Plus SSXI, K041834
Predicate Device #3:	Generic X-Ray film/screen, a pre-amendment device

Device Description 807.92(a)(4)

The BELMAX CM Model X168 X-Ray System is the next generation of the Takara Belmont digital dental X-ray systems. Similar to the prior Takara Belmont ANA-BEL, ANA-BEL CM equipped with the Takara Belmont ADR Plus SSXI, the BELMAX CM Model X168 X-Ray System offers digital imaging with panoramic and cephalometric imaging programs with the same exposure levels (kV/mA). Modifications resulting in the device include a new sized CCD sensor including three rather than two of the same sensor array grids mounted in a removable cartridge rather than bolted in place.

Device Intended Use 807.92(a)(5)

The BELMAX CM Model X168 X-Ray System is an extraoral source dental panoramic and cephalometric X-ray System intended to produce X-rays for dental radiographic examination and diagnosis of disease of the teeth, jaw, and oral structures.

Device Technological Characteristics 807.92(a)(6)

BELMAX CM, Takara ANA-BEL and ANA-BEL CM with Takara ADR Plus SSXI Imaging Device all employ X-ray tube with maximum rated peak tube potential of 90 kV, and a CCD digital acquisition sensor in a replacement film cassette. Digital processing is used.

Nonclinical and Clinical Tests 807.92(b)

Nonclinical Tests Discussion 807.92(b)(1)

The nonclinical tests included

- physical characteristics unique to the BELMAX CM, such as tolerance limits and effects of power noise on the operation of the device
- operational function tests such as procedure for taking an exposure
- functional characteristics such as plotting of the latent image decay characteristic as a function of time and temperature, recovery time for radiographic device to be able to accept the next exposure
- exposure characteristics such as quantitative measurements of the input dose required to generate an image equivalent to that provided by a predicate device
- safety features such as a ready signal provided to indicate the SSXI is prepared to accept and process an X-ray input

Clinical Tests Discussion 807.92(b)(2)

A clinical trial was sponsored and conducted by the Department of Oral Radiology, Asahi University School of Dentistry and included 30 patients receiving a dental examination. Readings were performed by five specialists in orthodontic dentistry. Digital images were observed on a computer monitor using the contrast, brightness, and magnification adjustment function of the ANA-BEL CM software, while X-ray films were observed on a conventional view box.

On BELMAX CM digital images, skeletal hard tissue structures were clearly observed in 97% of the subjects, whereas this fell to 81% for film images. For the depiction of soft tissue structures, 87% of BELMAX CM digital images were rated as sufficient whereas only 43% for film images. The BELMAX CM digital images were rated better than the film images on overall image quality. For landmark identification, the average percentage of sufficient clarity on BELMAX CM digital images was 93.6% and on X-ray film images it was 81.6%.

The BELMAX CM digital images were rated better than the film images for landmark identification.

Statement of Compliance with Federal X-ray Performance Standards

The BELMAX CM Model X168 X-Ray System is in compliance with the Federal X-ray performance standards.

Conclusion 807.92(b)(3)

The modified device has the same intended use and principle of operation as the prior Takara Belmont devices, as well as substantially equivalent technical specifications. The modifications were implemented to improve the ease of use, maintenance, and image quality, and do not change the intended use or fundamental scientific technology of the device. A hazard analysis, validation testing and clinical study against the generic X-ray film/screen predicate similar to those submitted for the prior Takara Belmont devices were presented to support the substantial equivalence of the modified Takara Belmont system.

The conclusions drawn from the nonclinical and clinical tests demonstrate that the BELMAX CM Model X168 X-Ray System is as safe, as effective and performs as well as or better than the Takara ANA-BEL and ANA-BEL CM Panoramic X-ray system with Takara ADR Plus SSXI Imaging Device and than the Generic X-Ray film.

The BELMAX CM, Takara ANA-BEL and ANA-BEL CM Panoramic X-ray system with Takara ADR Plus SSXI Imaging Device and with the Generic X-Ray film are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT - 5 2006

Takara Belmont USA, Inc.
Dr. Robert Schiff
c/o Schiff & Company
1129 Bloomfield Avenue
WEST CALDWELL NJ 07006

Re: K062529
Trade/Device Name: BELMAC CM, Model X168
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: August 28, 2006
Received: August 29, 2006

Dear Dr. Robert Schiff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K062529 ~~Not assigned yet~~
Device Name: BELMAX CM

Indications for Use:

The BELMAX CM dental panoramic and cephalometric X-ray system is indicated for use as a generator of radiographic images of the dento-maxilofacial region and is intended for dental examination and diagnosis of diseases of the teeth, jaw, and oral structures.

Prescription Use X

(Per 21 CFR 801 Subpart D)

Over-The-Counter Use _____

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lageman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062529